IN THE CIRCUIT COURT OF SAINT LOUIS COUNTY
STATE OF MISSOURI

SOUTHAMPTON COMMUNITY HEALTHCARE, formerly known as SOUTHAMPTON HEALTHCARE, INC.; KELLY STORCK; A.S., as next friend and on behalf of her minor child R.S.; N.F., as next friend and on behalf of his minor child A.F.; and LOGAN CASEY;

Plaintiffs,

v.

ANDREW BAILEY, in his official capacity as Attorney General for the State of Missouri,

207 West High Street,
Jefferson City, MO 65102,

Defendant.

Case No. _____

Division: _____

PETITION FOR A TEMPORARY RESTRAINING ORDER, INJUNCTIVE RELIEF, AND DECLARATORY RELIEF

INTRODUCTION

1. On April 13, 2023, Andrew Bailey, Attorney General of Missouri ("Defendant" or "Defendant Bailey"), submitted a proposed Emergency Rule, 15 C.S.R. 60-17.010 Experimental Interventions to Treat Gender Dysphoria ("Emergency Rule"), to Jay Ashcroft, Secretary of State, for review and approval. Attached hereto as **Exhibit A**.

2. Attached to the proposed Emergency Rule is a Declaration of Public Cost and a Fiscal Note Private Cost. *See Id*.

3. The proposed rule, if approved and published, will take effect on April 27, 2023.

4. The Attorney General claims authority to enact this Emergency Rule pursuant to the Missouri Merchandising Practices Act, Chapter 407, RSMo. ("MMPA").[1]

5. The Attorney General is an "agency" as articulated under § 536.010(1) and (8) because it is an administrative officer of the State authorized by law to make rules. Section 407.145 grants authority to the Attorney General to promulgate rules subject to the provisions of Chapter 536.

6. Pursuant to § 536.053, any person aggrieved by any rule promulgated by a state agency has standing to challenge any such rule and may bring such action pursuant to § 536.050. There is no exhaustion requirement. *See* § 536.053.

7. By enacting the Emergency Rule, the Attorney General is attempting to legislate the oversight, administration, and access to medical care for transgender Missourians. He estimates there are approximately 12,400 transgender people in Missouri over the age of 13. The Emergency Rule applies to both adolescents and adults.

8. However, volumes of empirical evidence and decades of clinical experience demonstrate that medical care for the treatment of gender dysphoria, also known as gender-affirming care, is medically necessary, safe, and effective for both transgender adolescents and adults with gender dysphoria. Indeed, it is the prevailing standard of care, accepted and supported by every major medical organization in the United States.

9. Notwithstanding the vast amount of experience and evidence supporting the provision of gender-affirming care, Defendant, without the authority to do so, adopted the Emergency Rule. The Rule targets gender-affirming care with unprecedented and unique restrictions so onerous that

[1] All statutory citations are to Missouri Revised Statutes (2016), as updated, unless otherwise noted.

it effectively prohibits the provision of this necessary, safe, and effective care for many, if not most, transgender people in Missouri.

10. Never before has an Attorney General sought to regulate the practice of medicine, let alone in this way, in Missouri. Yet, usurping authority and powers outside those of his office, Defendant claims expansive authority under the MMPA to regulate the practice of medicine. At most, however, the MMPA is a wafer-thin reed upon which to attempt to rest such sweeping power.

11. Defendant has exceeded his authority. The type of health care that the Emergency Rule attempts to restrict, prohibit, and regulate has been provided in the United States, including in Missouri, for decades.

12. The Emergency Rule interferes with the ability of medical and mental health providers to follow these evidence-based protocols. In so doing, the Emergency Rule denies transgender adolescents and adults medically necessary treatment and prevents parents from exercising their fundamental rights to obtain medically necessary care for their adolescents. It further regulates doctors and mental health providers and prohibits them from treating their patients in accordance with well-established standards of care.

13. Additionally, the Attorney General promulgated the Emergency Rule almost a month after announcing it, which undermines any supposed emergency basis for it, and only emphasizes the truth: there is no emergency.

JURISDICTION AND VENUE

14. This Court maintains original subject-matter jurisdiction over this action under Sections 526.030 and 527.010 of the Missouri Revised Statutes and Missouri Rule of Civil Procedure 87.01.

15. An action for declaratory judgment regarding a regulation or other agency interpretation of a statute may be brought in the county of a plaintiff's residence. § 536.050. Venue is proper in this Court because at least one of the Plaintiffs is a resident of St. Louis County.

PARTIES

A. Plaintiffs

16. Plaintiff Southampton Community Healthcare, formerly known as Southampton Healthcare, Inc. ("Southampton Healthcare"), is a nonprofit medical practice located and doing business in the City of St. Louis, Missouri. Southampton Healthcare provides treatment for gender dysphoria to transgender individuals, including the prescription of hormone therapy. The provision of medical care by providers at Southampton Healthcare to transgender individuals will be impacted by the Emergency Rule.

17. Plaintiff Kelly Storck is a licensed clinical social worker ("LCSW") with twenty-five years of clinical experience and fifteen years of experience specifically working with transgender, non-binary, and people questioning their gender identity. She is a resident of St. Louis City, Missouri. Plaintiff Storck provides individual therapy and assistance with gender care needs, including gender identity exploration, family and partner relationships, social transition, and information about medical options. She also, where appropriate and consistent with the WPATH Standards of Care, assesses clients for gender-affirming care and provides letters of support. Ms. Storck's mental health treatment of transgender individuals will be impacted by the Emergency Rule.

18. Plaintiff A.S., and her minor child, R.S., who is a fifteen-year-old transgender girl, are residents of Boone County, Missouri. R.S. has been diagnosed with gender dysphoria and has been

receiving and is seeking additional medically necessary care that will be impacted by the Emergency Rule.

19. Plaintiff N.F., and his minor child, A.F., who is a thirteen-year-old transgender girl, are residents of St. Louis County, Missouri. A.F. has been diagnosed with gender dysphoria and has been receiving and is seeking additional medically necessary care that will be impacted by the Emergency Rule.

20. Plaintiff Logan Casey, PhD, is a resident of St. Louis City, Missouri. Dr. Casey is a transgender adult man and has been receiving medically necessary care since 2010 that will be impacted by the Emergency Rule.

B. Defendant

21. Defendant Andrew Bailey is sued in his official capacity as the Attorney General of the State of Missouri. As Attorney General, Bailey has submitted the Emergency Rule restricting, regulating, and prohibiting gender-affirming health care pursuant to his purported authority under the MMPA.

GENERAL FACTUAL ALLEGATIONS

Background on Gender Dysphoria and its Treatment

22. Gender identity refers to a person's core sense of belonging to a particular gender, such as male or female. Every person has a gender identity.

23. Living in a manner consistent with one's gender identity is critical to the health and well-being of any person, including transgender people.

24. A person's gender identity is a fundamental aspect of human development. There is a general medical consensus that there are significant biological bases for gender identity.

25. A person's gender identity usually matches the sex they were designated at birth based on the appearance of their external genitalia. The terms "sex designated at birth" or "sex assigned at birth" are more precise than the term "biological sex" because all of the physiological aspects of a person's sex are not always aligned with each other.[2]

26. Transgender people have a gender identity that differs from the sex they were designated at birth. A transgender boy or man is someone who has a male gender identity but was designated a female sex at birth. A transgender girl or woman is someone who has a female gender identity but was designated a male sex at birth.

27. Gender dysphoria is the clinical diagnosis for the significant distress that results from the incongruity between one's gender identity and sex they were designated at birth. It is a serious medical condition, and it is codified in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* (DSM-5-TR) (DSM-5 released in 2013 and DSM-5-TR released in 2022).

28. Being transgender is not itself a medical condition to be cured. But gender dysphoria is a serious medical condition that, if left untreated, can result in debilitating anxiety, severe depression, self-harm, and suicide.

29. The World Professional Association for Transgender Health ("WPATH") has issued *Standards of Care for the Health of Transgender and Gender Diverse People* ("WPATH Standards of Care" or "SOC 8") since 1979. The current version is SOC 8, published in 2022.[3]

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[2] For these reasons, the Endocrine Society, an international medical organization representing over 18,000 endocrinology researchers and clinicians, warns practitioners that the terms "biological sex" and "biological male or female" are imprecise and should be avoided.

[3] *See* E. Coleman, et al., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, 23 International Journal of Transgender Health S1, S1-S259 (2022), https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644 ("WPATH Standards of Care" or "SOC 8").

30. The WPATH Standards of Care provide guidelines for multidisciplinary care of transgender individuals, including adults and adolescents, and describe criteria for medical interventions to treat gender dysphoria—including puberty-delaying medication, hormone treatment, and surgery when medically indicated—for adolescents and adults.

31. Every major medical organization in the United States recognizes that these treatments can be medically necessary to treat gender dysphoria.

32. The SOC 8 is based upon a rigorous and methodological evidence-based approach. Its recommendations are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options, as well as expert consensus. The SOC 8 incorporates recommendations on clinical practice guideline development from the National Academies of Medicine and the World Health Organization.

33. SOC 8's recommendations were graded using a modified GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) methodology considering the available evidence supporting interventions, risks and harms, and feasibility and acceptability.

34. A clinical practice guideline from the Endocrine Society (the "Endocrine Society Guidelines") provides protocols for the medically necessary treatment of gender dysphoria similar to those outlined in the WPATH Standards of Care.[4]

35. The guidelines for the treatment of gender dysphoria outlined in the WPATH Standards of Care and in the Endocrine Society Guidelines are comparable to guidelines that medical providers use to treat other conditions.

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[4] *See* Wylie C. Hembree, et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline*, 102 J. Clinical Endocrinology & Metabolism 3869, 3875 (2017), https://academic.oup.com/jcem/article/102/11/3869/4157558 (hereinafter "Endocrine Society Guidelines").

36. Doctors in Missouri and throughout the country follow these widely accepted guidelines to diagnose and treat people with gender dysphoria.

37. Medical guidance to clinicians differs depending on whether the treatment is for a pre-pubertal person, an adolescent, or an adult. In every case, the precise treatment recommended for gender dysphoria will depend upon each person's individualized needs.

38. Before puberty, gender-affirming care does not include any pharmaceutical or surgical intervention. Care for pre-pubertal adolescents may include "social transition," which means supporting them living consistently with their persistently-expressed gender identity. Such care might include support around adopting a new name and pronouns, wearing clothes that feel more appropriate to a particular gender, and changing one's hairstyle.

39. Under SOC 8 and the Endocrine Society Guidelines, medical interventions may become medically necessary and appropriate as transgender adolescents reach puberty. In providing medical treatments to adolescents, pediatric endocrinologists and other clinicians work with qualified mental health professionals experienced in diagnosing and treating gender dysphoria.

Puberty-Delaying Treatment

40. For many transgender adolescents, going through puberty in accordance with the sex designated to them at birth can cause extreme distress. For these adolescents, puberty-delaying medication (also sometimes referred to as "puberty blockers")—known as gonadotropin-releasing hormone ("GnRH") agonists—can minimize and potentially prevent the heightened gender dysphoria and permanent, unwanted physical changes that puberty would cause.

41. Under the Endocrine Society Guidelines, transgender adolescents may be eligible for puberty-delaying treatment if:

- A qualified mental health professional has confirmed that:

  - the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria;
  - gender dysphoria worsened with the onset of puberty;
  - any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; and
  - the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment.

- The adolescent:

  - has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility; and
  - has given informed consent, and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable law) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.

- And a pediatric endocrinologist or other clinician experienced in pubertal assessment:

  - agrees with the indication for GnRH agonist treatment;
  - has confirmed that puberty has started in the adolescent; and
  - has confirmed that there are no medical contraindications to GnRH agonist treatment.

42. Puberty-delaying treatment has been shown to be safe and effective at treating gender dysphoria in adolescents.

43. Puberty-delaying treatment works by pausing a person's endogenous puberty at the stage of pubertal development that the person is in at the time of treatment. For transgender girls, this treatment pauses the physiological changes typical of male puberty and prevents the development of associated secondary sex characteristics like facial hair and a pronounced "Adam's apple." It also prevents the deepening of the young person's voice and genital growth. For transgender boys, puberty-delaying treatment prevents the development of breasts and menstruation. The use of these interventions after the onset of puberty can eliminate or reduce the need for surgery later in life.

44. If gender-affirming hormones are prescribed to initiate hormonal puberty consistent with gender identity after puberty-delaying treatment, transgender adolescents will develop secondary sex characteristics typical of peers with their gender identity.

45. On its own, puberty-delaying treatment does not permanently affect fertility.

46. Because puberty-delaying treatment followed by gender-affirming hormone therapy can affect fertility, patients are counseled about the risks and benefits of treatment and provided information about fertility preservation.

47. Puberty-delaying treatment is reversible. If puberty-delaying treatment is stopped and no gender-affirming hormone therapy is provided, there are no lasting effects of treatment. Endogenous puberty resumes and patients undergo puberty in a timeline typical of their peers.

48. If gender-affirming hormone treatment is provided after puberty-delaying treatment, patients undergo puberty consistent with their gender identity on a timeline typical of their peers.

49. A significant body of scientific research shows that puberty-delaying medications are safe and effective and help improve psychological functioning and quality of life in transgender adolescents.

Hormone Therapy

50. For some adolescents and adults, it may be medically necessary and appropriate to treat their gender dysphoria with gender-affirming hormone therapy (testosterone for transgender boys, and testosterone suppression and estrogen for transgender girls).

51. Under the Endocrine Society Guidelines, transgender adolescents may be eligible for gender-affirming hormone therapy if:

- A qualified mental health professional has confirmed:
    - the persistence of gender dysphoria; and

  - any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's environment and functioning are stable enough to start sex hormone treatment.

- The adolescent:

  - has been informed of the partly irreversible effects and side effects of treatment (including potential loss of fertility and options to preserve fertility);
  - the adolescent has sufficient mental capacity to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to the treatment; and
  - has given informed consent, and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable laws) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.

- And a pediatric endocrinologist or other clinician experienced in pubertal induction:

  - agrees with the indication for sex hormone treatment; and
  - has confirmed that there are no medical contraindications to sex hormone treatment.

52. Under the Endocrine Society Guidelines, transgender adults may be eligible for gender-affirming hormone therapy if:

- There is persistent, well-documented gender dysphoria/gender incongruence;
- The patient has the capacity to make a fully informed decision and to consent for treatment;
- The patient is of the age of majority; and
- Mental health concerns, if present, are reasonably well controlled.

53. For transgender boys and men, hormone therapy involves treatment with testosterone. For transgender girls and women, hormone therapy involves treatment with testosterone suppression and estrogen. Hormone therapy can have significant masculinizing or feminizing effects and can assist in bringing transgender people's secondary sex characteristics into alignment with their gender identity, and, therefore, is medically necessary care for transgender people who need it to treat their gender dysphoria. Decades of clinical experience and research has shown

gender-affirming hormone therapy to be safe and effective at treating gender dysphoria in adolescents and adults.

Surgery

54. Some transgender individuals need surgical interventions to treat their gender dysphoria and help bring their phenotype into alignment with their gender. Though not all transgender people require or seek gender-affirming surgical care, such care can be medically necessary when in the best interests of the patient and supported by empirical evidence.

55. The current WPATH Standards of Care recommend that surgical interventions may occur only when appropriate for an individual. Surgery is typically not recommended for adolescents, though some older transgender male adolescents may undergo chest surgery.

56. Decades of research confirms that gender-affirming surgery is therapeutic and, therefore, an effective treatment for gender dysphoria.

The Emergency Rule

57. If approved by the Secretary of State, the Emergency Rule will take effect on April 27, 2023, just 10 business days after it was submitted for review and disclosed to the public including all Missourians who will be harmed by its provisions.

58. Defendant stated his intent to enact the Emergency Rule on March 20, 2023, yet he waited until April 13, 2023, to submit it to the Secretary of State, and then submitted a rule that included significant differences and expansions from what was announced he intended to do in March.

59. The Emergency Rule is an attempt by Defendant to usurp the power of the legislature and to regulate the provision of medical care in Missouri.

60. The Emergency Rule runs afoul of the statutory and Constitutional limits on powers of the Attorney General.

61. The Emergency Rule tramples the rights of transgender adolescents and their parents, transgender adults, and medical and mental health professionals who provide vital care to transgender individuals.

62. The Emergency Rule prohibits, restricts, and regulates the provision of medically-necessary, safe, effective, evidence-based, and potentially lifesaving health care to transgender adolescents and adults.

63. The Emergency Rule will disrupt and prevent medical care for thousands of Missourians, including Plaintiffs R.S., A.F., and Logan Casey, and will cause severe and irreparable harm.

64. The Emergency Rule will prevent medical and mental health professionals, including the provider Plaintiffs Southampton Healthcare and Emily Storck, from providing needed care and services to their patients and clients.

65. The Emergency Rule's "emergency statement" acknowledges that transgender individuals can and should be able to obtain care in Missouri in the form of psychotherapy.

66. However, the Emergency Rule then attempts to create and define an "emergency" with respect to the provision of well-established medical protocols and interventions that have been followed in Missouri and around the country and world for decades.

67. To support the claim of an "emergency," the Defendant asserts—incorrectly and without citation—that "in recent years, the use of other forms of interventions, often without any talk therapy at all, has accelerated exponentially."

68. Gender-affirming medical care has a long history in the United States and has been provided and studied for decades.

69. These decades of clinical experience and research have shown that gender-affirming health care, including puberty-delaying medications, hormones, and surgery, is safe, effective, essential. and improves the health, well-being, and quality of life of individuals, including adolescents and adults, with gender dysphoria.

70. Moreover, all of the treatments prohibited by the Emergency Rule are permitted when undertaken for reasons other than to affirm a gender identity that differs from a patient's sex designated at birth.

71. In other words, the Rule requires medical profssionals to reject well-established standards of care simply because their patient is transgender.

72. For instance, puberty-delaying medication is commonly used to treat central precocious puberty. Central precocious puberty is the premature initiation of puberty by the central nervous system—before 8 years of age in people designated female at birth, and before 9 years of age in people designated male. When untreated, central precocious puberty can lead to the impairment of final adult height, as well as antisocial behavior and lower academic achievement. The Emergency Rule permits puberty-delaying treatment for central precocious puberty.

73. The risk and occurrence of side effects of the proscribed treatments are comparable when used to treat gender dysphoria and when used to treat other conditions. In each circumstance, doctors advise patients and their parents about the risks and benefits of treatment and tailor recommendations to the individual patient's needs. For minors, parents consent to treatment and the patient gives their assent.

74. In support of the purported "emergency" related to this type of medical care that has been provided to transgender individuals for decades, Defendant's Emergency Rule states, without citation:

> This emergency rule is necessary to protect the public health, safety, and welfare, and also to protect a compelling governmental interest as the attorney general is charged with protecting consumers, including minors, from harm and investigating fraud and abuse in the state's health care payment system. Among other reasons, the recent immense increase in the use of these life-altering interventions, which have serious side effects, as well as the recent acknowledgment that these interventions are used in circumstances not supported by solid evidence, makes this issue time sensitive. Further, and independently, a whistleblower has issued a sworn affidavit, alleging that a prominent provider of these interventions in Missouri is systemically failing to comply with the medical standard of care, and an investigation has revealed that some providers in Missouri prescribe gender transition interventions without any individualized assessment, contrary to safeguards established in scientific literature and by medical organizations.
>
> As a result, the attorney general finds that this emergency action is needed because of a compelling governmental interest and a need to protect the public health, safety, and welfare. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Attorney General believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed April 13, 2023, becomes effective April 27, 2023, and expires February 6, 2024.

Exhibit A.

75. However, Washington University Transgender Center—presumably the "prominent provider" vaguely referenced by Defendant—has investigated and refuted all of the false claims made against it and relied on by Defendant. The report of investigation is attached hereto as **Exhibit B**.

76. A week after the issuance of the Emergency Rule by Defendant, Secretary of State Ashcroft publicly stated that he "wouldn't want to be the attorney that was defending it."[5]

77. Secretary of State Ashcroft – himself a former Missouri Attorney General – "wasn't confident [Defendant] had the authority to limit [gender-affirming] care."[6]

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[5] Jason Rosenbaum, *Att'y General Andrew Bailey's Restrictions on Gender-Affirming Care Will Affect Adults,* St. Louis Public Radio (Apr. 20, 2023), available at https://bityl.co/IKDP.
[6] Rosenbaum, *Att'y General Andrew Bailey's Restrictions on Gender-Affirming Care Will Affect Adults,*available at https://bityl.co/IKDP.

78. Indeed, Secretary of State Ashcroft opined that the Emergency Rule not only exceeded the Attorney General's authority, but also usurped the legislature's powers, stating: "If you are adding requirements that are not existent in the law, it seems to me that you are legislating."

79. In the same interview, Secretary of State Ashcroft commented that "If you're an adult, you have the capacity to make your own decisions," and that he "do[es]n't believe it's the role of government to forbid it."

The Emergency Rule Will Harm Transgender Missourians and Their Health Care Providers

80. The Emergency Rule will have devastating consequences for transgender adolescents and adults and their families, as well as health care providers in Missouri.

81. Transgender Missourians, including the individual Plaintiffs, Plaintiff Southhampton Healthcare's patients, and Plaintiff Storck's patients, will either be unable to obtain medical care, or be required to take medically unnecessary, unsupported, and burdensome steps to continue receiving treatment.

82. Untreated gender dysphoria can cause severe distress, anxiety, depression, and suicidality.

83. Cutting people off from treatment or withholding necessary care will inevitably cause significant and irreparable harm.

84. Withholding or restricting gender-affirming medical treatment from individuals with gender dysphoria when it is medically indicated puts them at risk of severe, irreversible harm to their health and well-being.

85. Individuals with gender dysphoria, including Plaintiffs R.S., A.F., and Logan Casey, if untreated, can suffer serious medical consequences, including possible self-harm and suicidal ideation.

86. Studies have found that as many as 40% of transgender people have attempted suicide at some point in their lives.

87. When adolescents are able to access puberty-delaying medication and hormone therapy, their distress recedes and their mental health improves.

88. Both clinical experience and medical studies confirm that, for many young people, this treatment dramatically improves patients' lives, and they go from experiencing pain and suffering to thriving. This has been the experience of Plaintiffs R.S. and A.F., who have benefitted greatly from treatment.

89. The effects of undergoing one's endogenous puberty may not be reversible even with subsequent hormone therapy and surgery in adulthood. For instance, bodily changes from puberty as to stature, bone structure, genital growth, voice, and breast development can be more difficult or even impossible to counteract. For the adolescent patients who are unable to access this gender-affirming medical care, this loss exacerbates lifelong gender dysphoria.

90. Medical treatment in adolescence can reduce life-long gender dysphoria, possibly eliminating the need for surgical intervention in adulthood, and can improve mental health outcomes significantly.

91. Gender-affirming medical care can be a lifesaving treatment for minors experiencing gender dysphoria. The major medical and mental health associations support the provision of such care, and recognize that the mental and physical health benefits to receiving this care outweigh the risks. These groups include the American Academy of Pediatrics, American Medical Association, the Endocrine Society, the Pediatric Endocrine Society, the American Psychological Association, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the National Association of Social Workers, and WPATH.

The Individual Plaintiffs

R.S.

92. R.S. is a fifteen-year-old eighth-grade girl who likes video games, plays tennis, and is an excellent student who consistently earns straight As. R.S. is transgender.

93. R.S. began therapy in May 2021 and was diagnosed with gender dysphoria in September 2021. R.S. has also been diagnosed with autism, anxiety, and ADHD all of which are ongoing diagnoses.

94. R.S. began her social transition in 2021 and began puberty-delaying medical treatment in early 2022, following the recommendations of her health providers and with the support of her parents.

95. To preserve fertility before initiating hormone treatment, and in consultation with her health providers, R.S. stopped taking puberty-delaying treatment in March 2023. Because R.S. would have to wait a minimum of three months after March 2023 before beginning a course of fertility preservation, R.S. and her family planned to begin hormone therapy this fall.

96. However, the Emergency Rule would prevent R.S. from obtaining hormone therapy until her mental health comorbidities are "resolved."

97. The Emergency Rule would also like make it impossible for R.S. to both preserve fertility and pursue hormone therapy according to this treatment plan, because in order to avail herself of the Rule's allowance for continuing a specific treatment that has already begun, R.S. would need to obtain hormone therapy *before* the effective date of the Rule.

A.F.

98. A.F. is a thirteen year-old transgender girl who lives with her parents and two siblings.

99. A.F., is now a seventh grader, and her parents remember her feeling discomfort with her sex assigned at birth and exhibiting outward signs of identifying as a girl as young as the age of two.

100. In April 2019, A.F.'s parents spoke to her school and teachers and informed them that she would be returning to fourth grade with a different name.

101. Pursuant to the advice of her health providers, and with the support of her parents, A.F. began medical care and therapy for gender dysphoria in 2019.

102. A.F. started puberty-delaying hormone treatment, Supprelin, in October 2021 after she began experiencing symptoms of puberty that were distressing, and exacerbated her gender dysphoria. Before receiving this treatment, A.F. was tested to determine whether she met the requirements to start them. A.F.'s Supprelin blocker is scheduled to be removed and replaced in June 2023.

103. A.F. has anxiety and depression that are managed through medication by her psychiatrist. Since January 2023, however, A.F. sees her psychiatrist every 3 to 4 weeks after experiencing a mild depressive episode that resulted from a worsening of her gender dysphoria when she began to witness her cisgender classmates undergoing puberty.

104. A.F.'s doctor will not allow her to initiate hormone therapy until six months after her thirteenth birthday, which will be in summer 2023, a few months after the Emergency Rule is set to go into effect.

105. However, the Emergency Rule will likely prevent A.F. from accessing the hormone therapy her doctors have recommended.

106. This is because she will not have undergone fifteen sessions of counseling within eighteen months before July 2023. and because her anxiety and depression are not "resolved."

107. A.F.'s parents have reviewed A.F.'s treatment records and concluded that A.F. will not have had 15 therapy sessions within the 18 months preceding the targeted start date for her hormone treatment, and so her treatment history fails to meet the Rule's therapy requirements.

108. These barriers to treatment defy the widely-accepted clinical practice guidelines that A.F.'s doctors followed when determining that A.F. should start hormone therapy to treat her gender dysphoria. Because of these barriers, 13 year old A.F. faces the threat of the harmful health repurcussions caused by Defendant's actions.

Logan Casey

109. Logan Casey, PhD, a thirty-six year-old transgender man, began provider-prescribed gender-affirming treatment in 2010 in the form of hormone therapy that he continues to this day, thirteen years later.

110. Mr. Casey had "top surgery" in 2010 and a hysterectomy in 2012.

111. Mr. Casey started seeing a therapist in 2009 to navigate his gender dysphoria and to obtain a letter of support, and continued in some form of therapy until 2020.

112. Mr. Casey has been diagnosed with ADHD, which he currently manages with medication.

113. Additionally, he reinitiated therapy in January 2023 to navigate difficult life changes and the resulting feelings of grief.

114. The Emergency Rule's requirement that comorbidities be "resolved" and for a specific amount of therapy sessions would threaten Mr. Casey's access to hormone therapy, which he has

taken continuously for well over a decade, because of the ADHD diagnosis he received more than two decades ago.

The Health Care Providers

115. Medical and mental health providers, including Plaintiffs Southampton Community Healthcare and Ms. Storck, will be required by the Emergency Rule to speak to and provide specific care for their patients as directed and ordered by Defendant—who is not a medical or mental health professional—that conflicts with their own medical and mental health training, education, and expertise; current medical and scientific knowledge; evidence-based clinical practice guidelines; and medical, ethical, or legal rules governing their professions.

116. The banned and regulated treatment is supported by a substantial body of research and clinical evidence; it is decidedly not experimental.

117. Moreover, other types of actually "experimental" treatments are permitted in Missouri. Wrongly labelling gender-affirming care as "experimental" cannot justify categorically banning only this one form of allegedly "experimental" treatment.

118. The gender-affirming care the Emergency Rule will restrict, prohibit, and regulate is all evidence-based and medically necessary for many transgender Missourians.

Southampton Community Healthcare

119. Southampton Community Healthcare ("Southampton Healthcare") is a nonprofit medical practice in St. Louis, Missouri.

120. Southampton Healthcare was established in 1986 by Dr. David Prelutsky, MD, after the physicians in the medical group to which Dr. Prelutsky belonged were not happy with him taking on HIV-positive patients and refused to remain professionally affiliated with him if he continued to take on and provide health care to HIV-positive patients.

121. Although Southampton Healthcare is a general primary care practice, it is known for providing affirming care to the LGBTQ+ community, communities most impacted by HIV, and those who are underinsured.

122. The practice consists of Dr. Prelutsky; Dr. Michael Donovan, MD; Dr. Sam Tochtrop, DO; Jeremy Dunbarr, PA-C; Aida Trivic, ANP-C; and Nicole Carr, FNP-C, all of whom are primary care providers.

123. Currently, Southampton Healthcare provides primary medical care including HIV care, sexual health services, reproductive health services, and gender-affirming health care to roughly 6,000-7,000, primarily adult, patients in the greater St. Louis area. Most of its patients identify as LGBTQ+. Nearly 700 of its patients are people living with HIV. And nearly 1,000 of its patients receive gender-affirming hormone treatment.

124. Southampton Healthcare medical professionals, including Dr. Donovan and Dr. Tochtrop, provide gender-affirming treatment to transgender people with gender dysphoria, following evidence-based clinical practice guidelines. They assess and diagnose "Gender Dysphoria in Adolescents and Adults" in accordance with the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* (DSM-5-TR), and provide treatment in accordance with WPATH's *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, and the Endocrine Society's Clinical Practice Guidelines.

125. While the vast majority of Southampton Healthcare's patients are adults, Southhampton Healthcare does provide treatment to a very small number of adolescent patients.

126. When treating gender dysphoria, health care providers use the same medications to treat transgender people as they use to treat non-transgender people with hormone deficiencies.

127. Following the issuance of the Emergency Rule, Southampton Healthcare received a flood of calls from patients who worry and fear that the Emergency Rule will affect their health care and the health care of their loved ones.

128. Southampton Healthcare providers are very concerned about the harmful effects the Emergency Rule may have on their transgender patients, as well as the Rule's harmful affect on ability to provide medical care consistent with their medical, ethical, and legal obligations.

129. The Emergency Rule endangers the health and wellbeing of Southampton Healthcare's transgender patients. It arbitrarily erects barriers to continue gender-affirming care for some of its patients. It places unnecessary and illogical barriers to gender-affirming hormone treatment for existing patients and prospective patients.

130. Given that gender dysphoria can cause clinically significant distress, delaying treatment for a patient's gender dysphoria risks not only exacerbating the patient's gender dysphoria, but also increasing the risk of depression, anxiety, and suicidality.

131. The Emergency Rule's blanket requirement that all patients receiving gender-affirming hormone treatment complete at least 15 mental health therapy sessions within 18 months presents an unnecessary and unattainable barrier for many of Southampton Healthcare's patients.

132. While Southampton Healthcare providers already assess all of their patients to see whether mental health therapy is necessary, not every transgender patient with gender dysphoria needs such prolonged therapy. Even for those patients who need therapy, Southampton Healthcare providers already face steep problems in connecting them to care because of the dearth of therapists in the region, and because of issues of affordability.

133. The Emergency Rule threatens to disintegrate trust in the patient-provider relationship Southampton Healthcare's providers have with their patients. This trust is essential to the provision

of health care, and especially so to patients belonging to historically marginalized groups, including transgender people. However, based on the text of the Emergency Rule, Southampton Healthcare's transgender patients have expressed to its providers that they fear they will be denied continuation of their hormone therapy if they share symptoms of other mental health issues.

134. This fear is so great amongst Southampton Healthcare's patients that many have reported suicidal ideation at the prospect of losing access to hormone treatment.

135. In addition, the restrictions, regulations, and prohibitions on treatment for gender dysphoria contained within the Emergency Rule stigmatize gender-affirming treatment and mental health treatment.

136. If patients do not feel they can be honest about their symptoms and medical needs, providers will miss serious health issues that could increase morbidities and cause negative health outcomes, including suicidality.

137. The Emergency Rule's required disclosures for informed consent before a patient can receive care, found in 15 C.S.R. 60-17.010(2)(B)1-23, are in direct conflict with medical evidence and the care that providers have been providing previously.

138. The 23 specific Defendant-created disclosures are required for all patients, not just minors, and are counter to best practices and known evidence of appropriate care.

139. The Emergency Rule's vague provisions also threaten Southampton Healthcare's ability to provide continuity of hormone therapy to its existing patients. While the Emergency Rule says that it does not apply to a "continuing prescription or provision of a specific intervention that has already begun," that is only "so long as the person or health organization promptly seeks to initiate the treatments and assessments called for by" subparagraphs (2)(C)–(K). The rule does not offer medical providers with any guidance as to what "promptly" means.

140. Some of Southampton Healthcare's patients have mental health comorbidities that are chronic and cannot be resolved. Under the Rule, Southampton Healthcare would be required to discontinue care for these patients.

141. Similarly, the Emergency Rule seems to imply that a patient who has been on gender-affirming hormones for years and does not require therapy must now attend 15 therapy sessions within 18 months in order to continue their care. Given the difficulties in accessing therapy, this requirement would lead to the discontinuation of hormone treatment even when therapy is not necessary for a patient.

142. The Emergency Rule also requires Southampton Healthcare providers to do repeated and continuous assessments for social contagion, even though there are no tests or assessment tools to conduct such a screening, social contagion is not a recognized medical phenomenon, and the vast majority of Southampton Healthcare's patients are adults.

143. The Emergency Rule also places significant costs on Southampton Healthcare.

144. In addition to the modifications required to Southampton Healthcare's informed consent processes and record keeping which will increase costs for Southampton Healthcare, other requirements of the Rule are impractical. For example, the Rule requires the maintenance of health care records and adverse effects of hormone therapy treatment for patients for 15 years after the initiation of gender-affirming care. This is impractical, particularly when a patient may leave care due to common changes or life events, such as changing health care providers due to a move.

145. Yet, notwithstanding the Emergency Rule's vague and impractical requirements or that many of its provisions conflict with current medical and scientific knowledge and evidence-based clinical practice guidelines, failure to comply with the Emergency Rule could result in criminal liability for Southampton Healthcare's providers.

146. This places Southampton Healthcare's providers in an untenable position. They must either comply with this arbitrary Rule – which conflicts with the evidence-based clinical guidelines and medical, ethical, and legal requirements they must follow – or risk criminal prosecution or civil liability.

Kelly Storck

147. Kelly Storck is a Licensed Clinical Social Worker with twenty-five years of clinical experience, including fifteen years specifically working with transgender and other LGBTQ+ young people.

148. Plaintiff Storck sees aproximately 75 and 100 clients per year, about 20 of whom are transgender or gender-diverse people under the age of 18. In a given month, approximately 60 to 70 percent of Plaintiff Storck's clients are transgender, non-binary, or queer.

149. Plaintiff Storck works extensively with young transgender people and their families. That work can include gender identity exploration, support through transition, navigating school and work, and accessing and building community, among other things.

150. It can also include assessing transgender clients of all ages for gender-affirming care consistent with the WPATH Standards of Care.

151. By establishing arbitrary requirements that patients must meet before accessing gender-affirming care, the Emergency Rule interferes with the practice of therapists like Plaintiff Kelly Storck, who perform assessments of transgender people and provide letters of support for accessing gender-affirming care. The Emergency Rule tells providers like Plaintiff Storck how they must perform their assessments, and requires them to deviate from the medically accepted standards of care according to which they practice.

152. The Emergency Rule also purports to regulate providers like Plaintiff Storck, who occasionally assess clients for gender-affirming care that they would pursue through another health care provider, in their own right by including within its ambit providers who "refer a patient" for gender-affirming care.

153. Plaintiff Storck assesses transgender clients according to the WPATH Standards of Care, but the Emergency Rule would require her to deviate from the standards of care and subject her clients to unnecessary and burdensome requirements during their assessments.

154. For example, the Emergency Rule's requirement that transgender people undergo 15 sessions of counseling over 18 months and its requirement that clients have a three year history of medically documented gender dysphoria force Plaintiff Storck to deviate from the Standards of Care and subject her clients to inappropriate, unneccessary, and harmful waiting periods that would create negative mental health consequences for many of her clients.

155. The Emergency Rule would force Plaintiff Storck, in her assessments, to subject her clients to burdensome and unnecessary screenings.

156. The Emergency Rule would prohibit Plaintiff Storck from providing a letter of support to a client whose mental health comorbidities were not "resolved." This would require Plaintiff Storck to withhold from her clients the very treatments that she has available to reduce the symptoms of conditions like anxiety and depression

157. Any purported interest in protecting transgender people from potential physical and emotional risks associated with the medical care cannot justify the Emergency Rule. The majority of potential risks and side effects related to puberty-delaying treatment, hormone therapy, and other treatment for gender dysphoria are comparable to those risks and side effects when such

treatments are used for other indications. Further, Missouri does not ban other forms of care carrying similar risks, such as treatments that carry fertility risks.

158. Every medical intervention carries potential risks and potential benefits. Weighing the potential benefits and risks of the treatment for gender dysphoria is a prudential judgment similar to other judgments made by health care providers, patients, and their parents (in the case of minors). Patients, and parents of patients, often make decisions about treatments with less evidence and/or greater risks than the treatments noted in the Emergency Rule.

159. The Emergency Rule subjects medical care for transgender Missourians to a double standard. It singles out such care for sweeping restrictions and prohibitions while permitting the same medical treatments carrying the same potential risks when prescribed to treat non-transgender patients for any other purpose.

LEGAL CLAIMS

160. No agency rule is valid if: "(1) There is an absence of statutory authority for the rule or any portion thereof; (2) The rule is in conflict with state law; or (3) The rule is so arbitrary and capricious as to create such substantial inequity as to be unreasonably burdensome on persons affected." § 536.014.

COUNT I

Violation of §§ 536.014, 536.021, and 536.025
noncompliance with rulemaking procedures, absence of authority, absence of emergency

161. Plaintiffs incorporate by reference all of the preceding paragraphs of this Petition as though fully set forth herein.

162. An agency's emergency rule and the agency's "findings and conclusions … in support of its employment of emergency procedures" are "judicially reviewable." § 536.025.6.

163. The Attorney General's findings and conclusions in support of the Emergency Rule are deeply flawed.

164. *First*, to bypass the notice-and-comment process, the Attorney General had to "[f]ind[] that an immediate danger to the public health, safety or welfare requires emergency action or the rule is necessary to preserve a compelling governmental interest that requires an early effective date[.]" § 536.025.1(1).

165. However, there is no immediate danger to the public health, safety, or welfare related to the provision of medical services to transgender people in Missouri. Accordingly, there is no emergency justification to bypass the notice-and-comment process.

166. *Second*, to bypass the notice-and-comment process, the Attorney General had to "[f]ollow[] procedures best calculated to assure fairness to all interested persons and parties under the circumstances." § 536.025.1(2).

167. The procedures followed in promulgating the Emergency Rule were not at all calculated to assure any fairness to all interested persons and parties, including Plaintiffs. And the Attorney General's conclusory statement stating otherwise is facially insufficient to bypass the notice-and-comment process.

168. *Third*, to bypass the notice-and-comment process, the Attorney General had to "[f]ollow[] procedures which comply with the protections extended by the Missouri and United States Constitutions," § 536.025.1(3), but the emergency procedures used here frustrate Plaintiffs' rights and traditional separation-of-powers principles.

169. *Fourth*, to bypass the notice-and-comment process, the Attorney General had to "[l]imit[] the scope of [the Emergency R]ule to the circumstances creating an emergency and requiring emergency action." § 536.025(4). The alleged circumstance creating the "emergency" is a now-

discredited purported whistleblower's affidavit addressing the gender-affirming care practices during a four-year period at a single pediatric treatment facility in St. Louis. Rather than limiting the Emergency Rule to the treatment facility, pediatric patients, or even the specific alleged "concerns" in the purported whistleblower's affidavit, the Attorney General seeks to expand restrictions on the practice of medicine beyond anything ever considered by the Legislature. For example, the impetus for the Emergency Rule was to solely protect minors, yet the plain text of the Rule states that it is intended to also apply to adults. The Emergency Rule provides no justification for its breath-taking scope under the circumstances.

170. In sum, there is no immediate danger to the public health, safety, or welfare related to the provision of gender-affirming care to transgender people in Missouri.

171. There is no emergency to justify using the procedures set forth in § 536.025 for bypassing the regular rulemaking processes.

172. The Emergency Rule is not necessary to preserve a compelling governmental interest that requires an early effective date.

173. The procedures followed in promulgating the Emergency Rule were not at all calculated to assure any fairness to all interested persons and parties, including Plaintiffs.

174. No constitutional protections have been extended.

175. Because there is no emergency, the Emergency Rule does not limit its scope to any circumstances creating an emergency.

176. The cost of compliance with the Emergency Rule will be much more than what the Attorney General has estimated.

177. For the foregoing reasons, the Emergency Rule should not be published or should be declared invalid because its underlying findings and conclusions justifying emergency action are

facially erroneous, and the Attorney General should be enjoined from implementing, enforcing, or applying the Rule.

COUNT II

Violation of §§ 536.014 and 407.020
lack of statutory authority and conflict with state law

178. Plaintiffs incorporate by reference paragraphs 1 through 160 as though fully set forth herein.

179. "Regulations may be promulgated only to the extent of and within the delegated authority of the enabling statute." *Brown v. Melahn*, 824 S.W.2d 930, 933 (Mo. App. E.D. 1992) (en banc). The Emergency Rule is invalid because the Attorney General lacks the statutory authority to promulgate the Rule. § 536.014(1).

180. The Attorney General claims rulemaking authority for the Emergency Rule from the MMPA. § 407.145.

181. Section 407.145 authorizes the Attorney General to "promulgate … all rules necessary to the administration and enforcement of the provisions of this chapter."

182. In construing § 407.145, the Missouri Supreme Court has limited the Attorney General's authority to "promulgate rules setting out the scope and meaning" of the MMPA. *Huch v. Charter Commc'ns, Inc.*, 290 S.W.3d 721, 724-25 (Mo. banc 2009) (citing *State ex rel. Nixon v. Telco Directory Pub.*, 863 S.W.2d 596, 601 (Mo. banc 1993) (attorney general's rulemaking authority is limited to "setting out the exact scope of [the MMPA] and the meaning of the words employed" therein).

183. The Emergency Rule does not allege what "merchandise" is being sold or offered in violation of the MMPA. *See* § 407.020.1 ("The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the

concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce …, in or from the state of Missouri, is declared to be an unlawful practice.").

184. Never before has the Attorney General taken this mere definitional or clarifying role to impose substantive requirements or restrictions on the practice of medicine.

185. Indeed, the MMPA does not contain a single reference to patient "health and safety" or standards of care, whereas such provisions are readily present in Chapter 197. *See, e.g.*, § 197.080. In fact, the Department of Health and Senior Services—i.e., the health care industry's regulator—is authorized to promulgate rules and regulations "with respect to all hospitals or different types of hospitals to be licensed hereunder as may be designed to further the accomplishment of the purposes of this law in promoting safe and adequate treatment of individuals in hospitals in the interest of public health, safety and welfare." *Id.*

186. These provisions in Chapter 197 would be meaningless if the Attorney General possessed similar rulemaking authority under the auspice of the MMPA. But the legislature doesn't pass meaningless laws.

187. Similarly, unlawful and unethical medical practices are regulated by the medical board. *See* § 334.100.

188. Indeed, medical malpractice is an area that is explicitly excluded from the reach of the MMPA. *See* § 407.025 ("No action may be brought under this section to recover damages for personal injury or death in which a claim can be made under chapter 538."). It is Chapter 538, not the MMPA, which applies to tort actions based on improper health care.

189. Moreover, the regulation of essential community providers ("ECPs") is expressly exempted from the Attorney General's enforcement powers under the MMPA. *See* § 407.020

("Nothing contained in this section shall apply to … [a]ny institution, company, or entity that is subject to chartering, licensing, or regulation by the director of the department of commerce and insurance under chapter 354 …."). The Emergency Rule makes no exception for ECPs.

190. Had the General Assembly intended to grant the Attorney General the authority he claims in the Emergency Rule, it would have said so expressly because "[t]he legislature 'does not … hide elephants in mouseholes.'" *R.M.A. by Appleberry v. Blue Springs R-IV Sch. Dist.*, 568 S.W.3d 420, 430 n.12 (Mo. banc 2019) (quoting *Whitman v. Am. Trucking Ass'ns.*, 531 U.S. 457, 468 (2001)).

191. That's because courts expect the legislative branch "to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance." *West Virginia v. E.P.A.*, 142 S. Ct. 2587, 2605 (2022) (quotation marks omitted). And it is indisputable that the Attorney General's Rule implicates significant economic and political considerations—both chambers of the General Assembly have passed legislation this session on the precise topic the Rule attempts to cover.

192. At bottom, our constitutional system "does not permit agencies to act unlawfully even in pursuit of desirable ends." *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2490 (2021) (per curiam).

193. The Attorney General lacks any authority under the MMPA to create or enforce standards of medical or mental health care as he is attempting to do through the Emergency Rule.

194. Further, the Emergency Rule otherwise conflicts with Missouri law and violates the rights of Plaintiffs.

195. For the foregoing reasons, the Emergency Rule should be declared invalid and the Attorney General enjoined from implementing, enforcing, or applying it.

COUNT III

Violation of § 536.014
arbirary and capricious

196. Plaintiffs incorporate by reference paragraphs 1 through 160 as though fully set forth herein.

197. A rule is invalid where, as here, it is "so arbitrary and capricious as to create such substantial inequity as to be unreasonably burdensome on persons affected." § 536.014(3).

198. The Emergency Rule constitutes a "'willful and unreasoning action, without consideration of and in disregard of the facts and circumstances.'" *Beverly Enterprises-Missouri Inc. v. Dep't of Soc. Services, Div. of Med. Services*, 349 S.W.3d 337, 345 (Mo. App. W.D. 2008) (quoting *Psychiatric Healthcare Corp. of Mo. v. Dep't of Soc. Servs.*, 100 S.W.3d 891, 900 (Mo. App. W.D. 2003)).

199. A rule is arbitrary and capricious when the agency has failed to engage in "reasoned decisionmaking." *Michigan v. E.P.A.*, 576 U.S. 743, 750 (2015). "Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." *Id.* (citation omitted). "It follows that agency action is lawful only if it rests on a consideration of the relevant factors." *Id.* (quotation marks omitted).

200. The Attorney General's "'findings are not based on substantial evidence.'" *Beverly Enterprises-Missouri Inc.*, 349 S.W.3d at 345 (quoting *Hundley v. Wenzel*, 59 S.W.3d 1, 8 (Mo. App. W.D.2001)).

201. The Attorney General has completely failed "to consider an important aspect[s] or factor[s] of the issue before it …." *Id.*

202. *First*, the Emergency Rule fails to accurately consider the cost associated with its implementation.

203. Fiscal notes must be reasonably accurate in order to place public and private entities on notice of their potential compliance costs. §§ 536.025.2, 536.200.1, 536.205.2.

204. The Emergency Rule estimates, in conclusory fashion, that it will "not cost state agencies or political subdivisions more than five hundred dollars ($500)" to implement the Rule. The Public Fiscal Note is facially invalid without any explanation in the Emergency Rule. *See* Exhibit A.

205. The Emergency Rule further estimates that it will "cost private entities less than five hundred ninety-nine thousand four hundred dollars ($599,400) to six hundred ninety-nine thousand three hundred dollars ($699,300)" to implement the Rule. *Id.*

206. On information and belief, compliance costs will be far greater than the Attorney General's estimates in the Emergency Rule.

207. These surprise compliance costs—costs that even the Attorney General concedes are "difficult to quantify"—will be unreasonably burdensome on the private and public entities that were entitled to rely on accurate information.

208. *Second*, the Emergency Rule's attempt to regulate medical and mental health care in Missouri is counter to and misrepresents the medical and scientific knowledge base surrounding gender dysphoria and gender-affirming care.

209. *Third*, the Emergency Rule conflicts with evidence-based clinical guidelines and medical, ethical, and legal requirements that health care providers must follow.

210. *Fourth*, the Emergency Rule failed to consider the harms that would be suffered by transgender people with gender dysphoria as a result of being denied gender-affirming care.

211. The Emergency Rule, therefore, is arbitrary and capricious for failing to consider these stakeholders' legitimate reliance interests in avoiding higher compliance costs. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 207 L. Ed. 2d 353, 140 S. Ct. 1891, 1913 (2020).

212. The Emergency Rule should be declared invalid, and the Attorney General enjoined from implementing, enforcing, or applying it.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask this Court to enter judgment against Defendant as follows:

A. Declare the Emergency Rule, 15 CSR 60-17.010, "Experimental Interventions to Treat Gender Dysphoria," invalid due to the Attorney General's lack of statutory authority to promulgate it;

B. Declare the Emergency Rule, 15 CSR 60-17.010, "Experimental Interventions to Treat Gender Dysphoria," arbitrary and capricious and, therefore, invalid;

C. Declare the findings and conclusions underlying the Emergency Rule, 15 CSR 60-17.010, "Experimental Interventions to Treat Gender Dysphoria," invalid;

D. Temporarily stay or suspend the April 27, 2023, effective date of the Emergency Rule, 15 CSR 60-17.010, "Experimental Interventions to Treat Gender Dysphoria";

E. Preliminarily and permanently enjoin the Attorney General from implementing, enforcing, or applying the Emergency Rule, 15 CSR 60-17.010, "Experimental Interventions to Treat Gender Dysphoria";

F. Order the Attorney General to immediately file the required notice under § 536.022.1 of the Court's judgment with the Secretary of State;

G. Award reasonable fees and expenses under § 536.025.10; and

H. Grant any and all other relief the Court deems just and proper.

Dated: April 24, 2023

Respectfully submitted,

By: */s/ J. Bennett Clark*

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* Application for admission *pro hac vice* forthcoming.

Attorneys for Plaintiffs

Exhibit A to Petition

15 CSR 60-17.010
Experimental Interventions
to Treat Gender Dysphoria

April 13, 2023

John R. Ashcroft
Secretary of State
Administrative Rules
RULE TRANSMITTAL

Administrative Rules Stamp

RECEIVED
APR 13 2023
Secretary of State
Administrative Rules

Rule Number **15 CSR 60-17.010 Experimental Interventions to Treat Gender Dysphoria**

Use a "SEPARATE" rule transmittal sheet for EACH individual rulemaking.

Name of person to call with questions about this rule:
Content **Todd A. Scott** Phone (573) 751-8366 FAX
Email address Todd.Scott@ago.mo.gov

Data Entry Phone FAX
Email address

Interagency mailing address **Office of the Attorney General, Supreme Court Building**

TYPE OF RULEMAKING ACTION TO BE TAKEN
☐ Emergency Rulemaking **X** Rule __ Amendment __ Rescission __ Termination
Effective Date for the Emergency **April 27, 2023**
☐ Proposed Rulemaking __ Rule __ Amendment __ Rescission
☐ Rule Action Notice ☐ In Addition ☐ Rule Under Consideration
☐ Request for Non-Substantive Change
☐ Statement of Actual Cost
☐ Order of Rulemaking __ Withdrawal __ Adopt __ Amendment __ Rescission
Effective Date for the Order
☐ Statutory 30 days OR Specific date
Does the Order of Rulemaking contain changes to the rule text? ☐ NO
☐ YES—LIST THE SECTIONS WITH CHANGES, including any deleted rule text:

Small Business Regulatory Fairness Board (DED) Stamp

JCAR Stamp

RECEIVED
By JCAR at 11:39 am, Apr 13, 2023

ATTORNEY GENERAL OF MISSOURI
ANDREW BAILEY

John R. Ashcroft
Secretary of State
Administrative Rules
600 West Main Street
Jefferson City, Missouri 65101

Re: *15 CSR 60-17.010 Experimental Interventions to Treat Gender Dysphoria*

Dear Secretary Ashcroft:

CERTIFICATION OF ADMINISTRATIVE RULE

I do hereby certify that the attached is an accurate and complete copy of the proposed rulemaking lawfully submitted by the Office of the Attorney General.

I further certify that this emergency rule is supported by a compelling governmental interest, the reasons for which are stated in the emergency statement.

Statutory Authority: sections 407.020, RSMo (Supp. 2022) and 407.145, RSMo (2016).

If there are any questions regarding the content of this proposed rulemaking, please contact:

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EXHIBIT A to Petition

ATTORNEY GENERAL OF MISSOURI
ANDREW BAILEY

Ms. Sarah Schappe
Director, Joint Committee on Administrative Rules
State Capitol, Room B8
Jefferson City, MO 65101

Re: *15 CSR 60-17.010 Experimental Interventions to Treat Gender Dysphoria*

Dear Director Schappe,

CERTIFICATION OF ADMINISTRATIVE RULE

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EXHIBIT A to Petition

EMERGENCY RULE
Title 15 – ELECTED OFFICIALS
Division 60 – Attorney General
Chapter 17 – Gender Transition Interventions

EMERGENCY RULE

15 CSR 60-17.010 Experimental Interventions to Treat Gender Dysphoria

PURPOSE: The attorney general administers and enforces the provisions of the Merchandising Practices Act, Chapter 407, RSMo. The attorney general may make rules necessary to the administration and enforcement of the provisions of Chapter 407, RSMo, and, in order to provide notice to the public, may specify the meaning of terms whether or not used in the Act. This rule specifies the meanings of certain terms used in the enforcement of the Act and provides notice to the public of their application. This rule does not contain an exhaustive list of practices that violate the Act. Instead, this rule identifies certain specific practices that violate section 407.020, RSMo.

EMERGENCY STATEMENT: Individuals of any age experiencing gender dysphoria or related conditions should be able to and are able to obtain care in Missouri. Often this care takes the form of psychotherapy, also known as talk therapy, rather than any chemical or surgical intervention. As the World Professional Association for Transgender Health has previously put it, this therapy often involves exploring the many influences on a person's gender identity, including "peer and other social relationships," and ensuring that "gender dysphoria is not secondary to, or better accounted for, by other diagnoses." WPATH, which describes itself as an organization "committed to advocacy" for certain "changes in public policies," has been criticized as an organization far too quick to recommend chemical or surgical intervention. Even still, the organization has "highly recommended" psychotherapy because psychotherapy can "greatly facilitate the resolution of gender dysphoria" and because, through this therapy, many "individuals integrate their trans- or cross-gender feelings into the gender role they were assigned at birth and do not feel the need to feminize or masculinize their body."

But in recent years, the use of other forms of interventions, often without any talk therapy at all, has accelerated exponentially. These include life-altering pubertal suppression, cross-sex hormone therapy, and gender transition surgery—all of which pose very serious side effects.

Many medical organizations have determined that these interventions—as currently practiced—lack solid evidentiary support. For example, Sweden's National Board of Health and Welfare recently declared that there is a "lack of reliable scientific evidence concerning the efficacy and the safety" of pubertal suppression and cross-sex hormone therapy and that "the risks" of these interventions "currently outweigh the possible benefits." Similarly, the U.S. Agency for Healthcare Research and Quality recently determined that "[t]here is a lack of current evidence-based guidance for the care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation." And

Finland has openly declared these interventions to be "an experimental practice." Because these gender transition interventions lack a solid evidentiary foundation and pose very serious side effects, they are unlawful under Missouri law absent sufficiently protective guardrails.

Part of the reason for the growing awareness of the lack of solid evidence is that many clinics have adopted practices that deviate substantially from the studies on which they say they rely. For example, although many clinics say that they rely on two Dutch studies to justify their practices, participants in those studies all received psychotherapy, and the studies excluded individuals with mental health comorbidities. Despite these and other limitations of the Dutch studies, some clinics have begun offering interventions to persons who would have been excluded from the Dutch protocol—such as persons experiencing significant mental health comorbidities—all without a comprehensive individualized assessment and often without any therapy at all directed at the patient's comorbidities. Even WPATH acknowledges the problem. Although WPATH is "committed to advocacy" of the "least restrictive" policies and "hope[s] that future research will explore the effectiveness of this model," it admits that "[t]here are no studies of the long-term outcomes of gender-related medical treatments for youth who have not undergone a comprehensive assessment."

This emergency rule is necessary to protect the public health, safety, and welfare, and also to protect a compelling governmental interest as the attorney general is charged with protecting consumers, including minors, from harm and investigating fraud and abuse in the state's health care payment system. Among other reasons, the recent immense increase in the use of these life-altering interventions, which have serious side effects, as well as the recent acknowledgment that these interventions are used in circumstances not supported by solid evidence, makes this issue time sensitive. Further, and independently, a whistleblower has issued a sworn affidavit, alleging that a prominent provider of these interventions in Missouri is systemically failing to comply with the medical standard of care, and an investigation has revealed that some providers in Missouri prescribe gender transition interventions without any individualized assessment, contrary to safeguards established in scientific literature and by medical organizations.

As a result, the attorney general finds that this emergency action is needed because of a compelling governmental interest and a need to protect the public health, safety, and welfare. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Attorney General believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed April 13, 2023, becomes effective April 27, 2023, and expires February 6, 2024.

(1) "**Covered Gender Transition Intervention**" or "**Intervention**" means the provision or prescription of any puberty-blocking drugs, cross-sex hormones, or surgery, for the purpose of transitioning gender, decreasing gender incongruence, or treating gender dysphoria, and does not include:

(A) treatment for a genetically or biochemically verifiable disorder of sex development such as 46, XX DSD; 46, XY DSD; sex chromosome DSDs; XX or XY sex reversal; or Ovotesticular disorder;
(B) treatment for precocious puberty; or
(C) for subparagraphs (2)(C)–(K), continuing prescription or provision of a specific intervention that has already begun, so long as the person or health organization promptly seeks to initiate the treatments and assessments called for by these subparagraphs.

(2) It is an unfair, deceptive, fraudulent, or otherwise unlawful practice for any person or health organization to provide a covered gender transition intervention to a patient (or refer a patient for such an intervention) if the person or health organization:
(A) Fails to assess (at least annually) whether the patient continues to have gender dysphoria;
(B) Fails to obtain informed consent by disclosing conspicuously—on its website, physically in writing, and orally in person by the prescribing provider—to the patient and (if the patient is a minor) to the patient's parents or legal guardians, by means of information that includes language materially identical to each point below, that:
1. The use of puberty blocker drugs or cross-sex hormones to treat gender dysphoria has been described as experimental by researchers and is not approved by the Food and Drug Administration (FDA);
2. The use of puberty blocker drugs or cross-sex hormones to treat gender dysphoria has been recognized by medical authorities in Europe, after independent reviews, to be experimental or lacking sufficient evidence and has been substantially restricted in countries such as Sweden, Finland, Norway, and the United Kingdom;
3. The U.S. Agency for Healthcare Research and Quality has determined, "There is a lack of current evidence-based guidance for the care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation";
4. A study spanning 5 decades of almost 5,000 transgender people who had received cross-sex hormones, regardless of treatment type, nevertheless showed a "two-fold increased mortality risk," which "did not decrease over time";
5. An article in the *International Review of Psychiatry* found that, according to ten different studies, the vast majority of children, 85.2%, experiencing gender dysphoria grew to become comfortable with their natal sex, and the Endocrine Society found that "the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/gender incongruent in adolescence";
6. A scientific article in the *Journal of Infant, Child, and Adolescent Psychotherapy* concluded that "encouraging mastectomy, ovariectomy, uterine extirpation, penile disablement, tracheal shave, the prescription of hormones which are out of line with the genetic make-up of the child, or puberty blockers, are all clinical practices which run an unacceptably high risk of doing harm";

7. Sweden's National Board of Health and Welfare ("NBHW") recently declared that, at least for minors, "the risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits";
8. A systematic review of the evidence by researchers in Europe regarding natal boys concluded that there is "insufficient evidence to determine the efficacy or safety of hormonal treatment" and that certain hormonal interventions can potentially cause or worsen depression;
9. One scientific study noted that an individual whose friend identifies as transgender is "more than 70 times" as likely to similarly identify as transgender, suggesting that many individuals may "incorrectly believe themselves to be transgender and in need of transition" because of social factors";
10. A follow-up study recently determined, "Youths with a history of mental health issues were especially likely to have taken steps to socially and medically transition";
11. A study of 1,655 parental reports found that "parents tended to rate their children as worse off after transition" and "that parents believed gender clinicians and clinics pressured the families toward transition";
12. The FDA has issued a warning that puberty blockers can lead to brain swelling and blindness;
13. Puberty is associated with profound developmental maturation of the brain, and researchers have expressed concern that interruption of normally timed puberty may therefore be harmful to the brain;
14. Multiple observational studies conclude that nearly all children prescribed puberty blockers for gender dysphoria have later been prescribed cross-sex hormones. For example, an independent review of gender transition interventions based on data from multiple countries determined that "almost all children and young people who are put on puberty blockers go on to sex hormone treatment";
15. After performing a systematic review, the Endocrine Society was unable to draw any conclusions on whether hormone therapy reduces death by suicide among individuals identifying as transgender;
16. A summary of available evidence written by medical societies "from around the globe" found that "there are no proven methods to preserve fertility in early pubertal transgender adolescents";
17. Researchers have suggested that allowing a child to go through puberty without medical intervention may resolve gender dysphoria, whereas puberty suppression may improperly influence and worsen gender dysphoria;
18. Puberty suppression presents a risk of stunted growth and failure to attain normal peak bone density;
19. There is a lack of understanding in the medical community of the causes of gender dysphoria, as well as an admission that more research is needed to fully understand the effects, especially long-term effects, of puberty suppression and cross-sex hormone treatment;

20. A significant number of children and adolescents who begin gender transition interventions desist in their desire to transition, although the actual number is unknown because of low rates of follow up;
21. The Endocrine Society has acknowledged that children experiencing gender dysphoria are more likely to identify with their natal sex if they do not socially transition;
22. The World Professional Association for Transgender Health ("WPATH") has acknowledged, "In most children, gender dysphoria will disappear before, or early in, puberty"; and
23. Many medical, hormonal, or surgical transition interventions are irreversible.

(C) Fails to ensure that, for at least the 3 most recent consecutive years, the patient has exhibited a medically documented, long-lasting, persistent and intense pattern of gender dysphoria;

(D) Fails to ensure that the patient has received a full psychological or psychiatric assessment, consisting of not fewer than 15 separate, hourly sessions (at least 10 of which must be with the same therapist) over the course of not fewer than 18 months to explore the developmental influences on the patient's current gender identity and to determine, among other things, whether the person has any mental health comorbidities;

(E) Fails to ensure that any psychiatric symptoms from existing mental health comorbidities of the patient have been treated and resolved;

(F) Fails to ensure that the patient has received a comprehensive screening to determine whether the patient has autism;

(G) Fails, with respect to a patient who is a minor, to ensure that the patient has received a comprehensive screening (at least annually) for social media addiction or compulsion and has not, for at least the six months prior to beginning any intervention, suffered from social media addiction or compulsion;

(H) Fails to ensure (at least annually) that the patient is not experiencing social contagion with respect to the patient's gender identity;

(I) Fails to adopt and follow a procedure to track all adverse effects (both expected and unexpected) that arise from any course of covered gender transition intervention for all patients beginning the first day of intervention and continuing for a period of not fewer than 15 years;

(J) Fails to maintain data about adverse effects in a form that can be accessed readily for systematic study; or

(K) Fails to obtain and keep on file informed written consent from the patient and (if the patient is a minor) from all parents or guardians who have authority to consent to medical intervention, as to each requirement of this section. Such written consent shall be obtained for each intervention after the disclosures required by subsection (2)(B) and renewed not less than quarterly for the first 3 years of such intervention (or until the age of majority for a patient less than 15 years old when such intervention begins), and not less than twice a year thereafter.

(3) Any person or health organization providing a covered gender transition intervention to a patient (or referring a patient for such an intervention) shall document and retain in

such patient's records a detailed description of compliance with the provisions of section (2).

(4) If any application of any provision, word, or clause to any person or circumstances is found by a court to be invalid, that application alone shall be severed and the remaining possible applications of every provision, word, and clause to all other persons and circumstances shall remain in force.

AUTHORITY: sections 407.020, RSMo (Supp. 2022), 407.145, RSMo (2016). Emergency rule filed April 13, 2023, effective April 27, 2023, expires February 6, 2024.

PUBLIC COST: This emergency rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the time the emergency is effective.

PRIVATE COST: This emergency rule will cost private entities less than $599,400 to $699,300 in the time the emergency is effective.

DECLARATION
OF PUBLIC COST

I, Rhonda Meyer, Deputy Chief of Staff to Andrew Bailey, Attorney General of the State of Missouri, do declare that it is my opinion that the cost of proposed rule 15 CSR 60-17.010, is less than five hundred dollars in the aggregate to this agency, any other agency of state government or any political subdivision thereof.

Rhonda Meyer
Deputy Chief of Staff
Missouri Attorney General

FISCAL NOTE
PRIVATE COST

I. Department Title: Title 15 - Elected Officials
Division Title: Division 60 - Attorney General
Chapter Title: Chapter 17 – Gender Transition Interventions

Rule Number and Title:	**15 CSR 60-17.010 Experimental Interventions to Treat Gender Dysphoria**
Type of Rulemaking:	**Emergency**

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
3 Specialty Gender Transition Clinics	**Hospitals and Centers**	**Less than $599,400 – $699,300**
Up to 1,869 Primary Care Providers or Standalone Clinics	**Clinics**	**Less than $599,400 – $699,300**
Up to 2,630 Pharmacies	**Pharmacies**	**Less than $599,400 – $699,300**

III. WORKSHEET

Number of Patients

The number of individuals in Missouri 13 or older who identify as transgender has been estimated by the Williams Institute at UCLA to be 12,400. Not all of these individuals desire or seek gender transition interventions. Some who do seek these interventions may seek only some of the possible interventions. Further, the regulation does not prohibit individuals who have already started an intervention from continuing the intervention.

Based on information obtained by the Attorney General's Office, the Pediatric Transgender Center at Washington University—which appears to have the highest patient total in the state—starts new interventions on about 300 different individuals per year. New interventions are much more likely among younger age cohorts than individuals who have lived decades of their lives without any interventions. Based on current figures, Missouri estimates that about 600-700 individuals in the state would begin a new intervention within the next 12 months. This emergency regulation lasts about 9 months, so an estimated 450-525 individuals would begin a new intervention during this time period.

Although some providers already comply with this regulation, this number (450-525) assumes for the sake of this fiscal note that no clinic is already complying with the regulation with respect to any individual. That assumption ensures maximum notice and eliminates any unfair surprise about fiscal cost.

Cost of Gender Transition Interventions

The cost of hormonal intervention can vary greatly in individual cases, but studies have assessed average costs across the population. A recent study in *The Journal of Law, Medicine & Ethics* determined that average total expense (out-of-pocket costs plus costs paid by a health plan) for hormonal intervention was $755. Baker, et al., *Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population* (2022).

Surgical intervention can be much more expensive but, unlike hormonal intervention, is not repeated year after year. The Baker study determined that the average total expense (out-of-pocket costs plus costs paid by a health plan) per person for surgical interventions was $41,236.

Weighting these figures according to the relative frequency (*e.g.*, hormones much more frequent than surgeries), the Baker study concluded that the average annual cost for hormonal interventions plus surgical interventions "combined" was $1,776 per person per year. Under the 9-month time frame of the emergency regulation, the average cost per person would be $1,332.

Total Cost = $599,400 – $699,300

IV. ASSUMPTIONS

Due to the emergency nature of the regulation and the relatively sparse studies in this area, many of the variables needed to precisely assess the cost are unknown or difficult to quantify.

Any possible decrease in revenue experienced by any of the clinical classes due to the emergency rule may be offset in part or in full by providing other services required by the regulation. The regulation requires adequate provision of mental health treatment, and many entities already represent themselves as providing a multidisciplinary approach to gender dysphoria, including by providing mental health services.

Similarly, any decrease in revenue experienced by pharmacies may be offset in part or in full by separate prescriptions aimed at treating mental health comorbidities that are not presently treated.

Additionally, due to the lack of available data in this field, it is unknown which class types will bear which portions of the cost. It is likely that each class type will bear varying percentages of the total costs.

The Pediatric Transgender Center in St. Louis provides the most new interventions in the state—up to half of the total new interventions.

The number of Primary Care Providers or Standalone Clinics is based on surveys that assessed the percentage of entities that would be willing to prescribe hormonal gender transition interventions. It represents the upper limit of how many of these entities might be affected, although the actual number affected is likely far less.

The effect on these entities is estimated to be comparatively lower because these entities provide gender transition interventions to a smaller percentage of the population and often continue interventions that other entities have already started. The regulation does not prohibit individuals who have already started an intervention from continuing the intervention.

Exhibit B to Petition

Washington University in St. Louis
Transgender Center
Internal Review – Summary of Conclusions

April 21, 2023

Washington University Transgender Center Internal Review
Summary of Conclusions
April 21, 2023

OVERVIEW

On February 9, 2023, an article published in the online media outlet The Free Press outlined a series of allegations of inappropriate conduct at the Washington University Transgender Center (the Center). The author of the article also made similar allegations directly to the Missouri Attorney General.

When the University became aware of these allegations on the day of the article's publication, Chancellor Andrew D. Martin immediately initiated a comprehensive analysis of procedures followed and care provided to patients and families at the Center. The University, in collaboration with St. Louis Children's Hospital, also created an Oversight Committee charged with weekly review of Center activities. The committee was also directed to provide additional education on consent procedures, adverse event reporting, and protection for employees, patients, family members, and other individuals who report concerns.

The allegations concerned Center practices involving the prescription of medication to patients under the age of 18, specifically with regard to parental consent and mental health evaluation; patient reactions to prescription medications; and gender-related surgeries on patients under the age of 18.

This report represents a summary of the University's conclusions.

REVIEW PROCESS

The University's focus has been on the allegations made, with a particular emphasis on allegations of patient harm and the consenting process. The University's goal was to ensure care provided at the Center is consistent with recognized standards of care. Specifically, the University was committed to ensuring the policies and procedures of the Center follow standards of care adopted by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society. Those standards have been recognized by the American Academy of Pediatrics, American Medical Association, and American Psychological Association.

In addition to reaching the conclusions described below, the University has also produced information and documents to state and federal officials who had opened their own inquiries into

the Center. The University provided a large number of documents to the Missouri Attorney General in response to his ongoing review; responded specifically to the allegations made about consenting, mental health treatment, and alleged patient harm; and also gathered information in response to questions from U.S. Senator Josh Hawley. The University has reached the following conclusions, which are described below.

CONCLUSIONS

After careful consideration over the course of a more than an eight-week period, the University has concluded that allegations of substandard care causing adverse outcomes for patients at the Center are unsubstantiated.

Washington University physicians and staff at the Center follow appropriate policies and procedures and treat patients according to the currently accepted standard of care, as recommended by the American Academy of Pediatrics and other nationally recognized organizations.

While not based on deviations from accepted practice or adverse outcomes for patients, the University has determined that a more detailed and formalized approach to the Center's process for documenting parental consent and obtaining custody documentation is warranted and that the University should take a more organized approach in responding to any requests of public engagement on the matter of transgender care. The University has committed to making these adjustments.

- A total of 1,165 patients have sought care at the Center since June 2018. These interactions range from an informational phone call to medical treatment but were of sufficient depth to create a medical record for each patient. All patients seen at the Center have a medical record.
- These patients account for approximately 6,000 visits to the Center for counseling and/or medical care during that time period. Note: Many patients visited the Center more than once and additional visits were made by patients to psychologists affiliated with the Center at St. Louis Children's Hospital.
- Of the Center's 1,165 patients, 531 received cross-sex hormones, including some who were initially on puberty blockers, some who were started on these medications by Center providers, and some who had existing prescriptions for these medications from unrelated physicians when they first arrived at the Center. An additional 67 patients were prescribed puberty blockers and not cross-sex hormones. The remainder (567 patients) were not prescribed puberty blockers or cross-sex hormones.

- Interviews with Center providers and a review of medical records identified no patients who had adverse physical reactions caused by medications prescribed by Center providers.

- Appropriate mental health assessment and/or intervention was, and is, required for all medical treatment provided to patients under the age of 18. The Center's practice is to require a letter of support from a licensed mental health provider who has treated the patient before prescribing puberty blockers or cross-sex hormones. Letters of support provided to the Center reflect individualized review and assessment of patients. Records indicate most patients had ongoing relationships with mental health providers and the Center providers recommend resources to patients who may need ongoing treatment for mental health concerns. Mental health care and counseling is a priority at the Center.

- Care for patients under the age of 18 is provided with appropriate and well-documented parental consent, as required by the University and the state of Missouri and consistent with the general practice for prescribing medication to minors by University physicians.

- The Center's practice includes obtaining and documenting consent from parents (including in instances where court orders governed which parent had authority to consent) or, when appropriate under the circumstances, from guardians.

- Center providers have not referred patients under 18 for gender-affirming surgery since late 2018 when the Center adopted a policy prohibiting these referrals. Upon request, some families were provided with the names of surgeons (including Washington University physicians) who provided such surgeries, and the Center's providers have provided summaries of care for patients desiring surgical interventions.

- There have been a total of six surgeries identified that were performed by Washington University physicians since 2018. These were all chest surgeries for adolescents transitioning to male. These were all referrals from other medical providers or patient-initiated self-referrals, not a result of direct Center provider referrals. As noted above, Center providers would provide summaries of care for patients to their surgeons. Chest masculinization surgery for minors is within the defined standard of care when clinically and developmentally appropriate as determined by an experienced multidisciplinary team

- Washington University physicians no longer perform gender-affirming surgeries on patients under the age of 18.

- The Center engaged in a number of educational and outreach seminars, often for groups of faculty and staff of public school districts. The University recognizes the need to provide education on the topic of gender affirming care and treatment and reasonable accommodations for transgender students. Given the sensitivity of these issues, the

University has determined that it would be helpful to introduce more internal oversight of these sessions.

RECOMMENDATIONS

While the University's review concluded that Washington University physicians adopted appropriate policies and procedures to treat patients according to the currently accepted standard of care, it also identified four areas for improvement. The University is making a commitment to the following:

- While appropriate parental consent has been obtained verbally and documented in the medical record, the additional protocols recommended by the Oversight Committee for documenting parental consent to ensure a consistent process is followed by all staff and physicians who interact with patients under age 18 should be made permanent. Specifically, the University has decided to take the additional step of requiring specific written consent prior to prescribing gender affirming medications. The University has reviewed the consenting process and made these updates to the Center's protocol.
- The Center has adopted a process of requiring a family to provide custody agreements before an initial visit at the Center by a patient under age 18. Prior practice had been to obtain the custody agreement before medical intervention in cases where decision-making authority was in question.
- The University has undertaken additional efforts to reaffirm its policy prohibiting gender-affirming surgery to the Departments of Pediatrics and Surgery.
- In addition to recommendations directly related to the allegations, the University also determined in the course of its review that there is an opportunity to be more intentional about public engagement on the topics of gender dysphoria and transgender care. The University will review its procedures for engaging with members of the community, particularly as it pertains to guidance provided to local school administrators and educators. Note: Public outreach by knowledgeable providers is within the WPATH standard of care.

The University is analyzing the impact of the Missouri Attorney General's emergency regulation of April 13, 2023.